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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,279	07/14/2003	Arthur M. Krieg	C1039.70077US00	8248

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EXAMINER

EPFS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/619,279	Applicant(s) KRIEG, ARTHUR M.	
	Examiner Anne Marie S. Wehbe	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-57 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 42-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 46-47, drawn to a number of permutations and/or combinations of X1, X2, and X3, and X4 as required for the generic formula as set forth in the linking claim 42.

Applicant is required to elect a specific combination of permutations as required at minimum for the formula, wherein each of the X1-X4 must be identified for a specific nucleotide residue.

Each of the sequences with a specific combination of permutations are distinct in its structure and is expected to generate a sequence dependent immunostimulatory effect.

A search of one specific set of permutations for the formula in the prior art does not necessarily overlap with that of another. Further, due to the specificity in structural requirement for each of the specific set of permutation, a sequence search would also be distinct for its of the encompassed sequences and does not appear to be solely affected by any common structure as set forth in the formula, let alone the fact that the formula encompasses an enormous number of <100 nucleotide containing CpG unmethylated sequences. Therefore, a search of a

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composition comprising anything more than a specific set of permutations is considered to be unduly burdensome to the examiner. For multiple inventions as set forth in claim 46, claim 42 is identified as the linking claims.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Should a specific set of permutations or combination of X1-X4 be elected, the

Elected set of combination/permutations is generic to a plurality of disclosed patentably distinct species comprising a specific sequence which is claimed specifically and listed in claim 52, and which is encompassed by the elected set of combination/permutations:

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from as indicated above, even though this requirement is traversed. Each of the listed species is directed to a specific sequence of nucleotide residues, which may or may not be encompassed by the formula with the elected set of permutations. The claimed invention is drawn to an immunostimulatory composition which is desired to be used in an *in vivo* subject, and thus, has a distinct set of variables affecting consideration and examination of each of the distinct immunostimulatory species of sequence. Thereby, a search and examination of anything more than one of such together for patentability would be unduly burdensome to the examiner.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **571-273-8300**.

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

